

Tetrachlorvinphos (TCVP) Updated Risk Picture

Internal, Deliberative – Do not cite



Briefing Objective

- Provide an overview of the risks identified in the registration review risk assessments

Outline

- Use and Usage
- Benefits
- Registration Actions - Onions
- Registration Review
 - Risk Assessment Overview
 - Proposed Mitigation
- Next Steps

Use

- TCVP is a organophosphate (OP) insecticide; the mode of action is neurotoxicity via acetyl cholinesterase (AChE) inhibition.
- There are two technical registrants: Hartz and Bayer, and 38 end-use registrations.
- Registered uses are on livestock and domestic animals or as a perimeter treatment. There are no agricultural uses
- The sole registrant for pet products (cats and dogs) is Hartz. Hartz has 11 end-use pet product registrations.
 - Pet products include flea and tick collars, powders, and pump sprays.
- Livestock and perimeter treatments include feed-through products, sprays, and dust powders for shaker can application.

Usage

- Pesticide usage on pets and public preference for different formulations will vary by regional and socioeconomic factors
- Owners of dogs are significantly more likely to purchase pet insecticides than cat owners with 77% of dog owners and 54% of cat owners reporting purchasing pet insecticides in 2011 (NAMD, 2012)
- Spot-on formulations are the primary formulation purchase for single and multi-family housing and mobile homes/trailer residents with minimum difference in percent usage(< 5%). Mobile home residents use more veterinary medicine, shampoo, pet collars, sprays, and powder/dust than single or multi-family residences.
- Liquid rub-in/spot-on products are the most commonly purchased form of pesticides applied to pets in the United States and has shown continued increased usage since 2005. In 2011, 50.3% of respondents reported spot-on use, an increase over the 46.3% usage reported in 2009 (Table 4) (NAMD, 2012).
- Veterinary medicines, shampoos, and collars were the other commonly purchased insecticide formulations with little difference in purchase preference (26.6, 25.2, and 25 .9% respectively in 2011). However, in contrast to the increased usage of spot-on products, usage of veterinary medicines, shampoos, and collars were noted to decrease between 2009 and 2011.
- There is little correlation in family income and choice of pet insecticide formulation. Nevertheless; families of all income levels prefer to purchase spot-on products over veterinary medicine (tablets), shampoo, and pet collars. Similarly, with the exception of incomes under \$25k and incomes between \$75k to

Absence of TCVP-based products for flea and tick control on dogs would limit pet collar availability for dogs to products containing amitraz (tick control only), deltamethrin, flumethrin+imidacloprid, and geraniol+peppermint oil+almond oil. Cat collars would be limited to flumethrin+imidacloprid and geraniol+peppermint oil+almond oil (Table 14).

Benefits

- Heading 1
 - Line 2
 - Line 4
 - Line 3
 -
- Heading 2
 - Line 2

Formetanate will control a wide range of insect pests. In these crops the primary targets are: Lygus, thrips, and mites.

*Although the acreage for alfalfa for seed is small, if viable seed is not produced, it impacts all alfalfa production

Because formetanate is one of the most expensive options for growers – those who use it are getting a benefit which BEAD cannot identify.

Alternatives to TCVP Pet Products (move slide to end?)

- The most likely alternative formulation to pet collars are spot-on products.
- Deltamethrin and flumethrin + imidacloprid are the only active ingredient alternatives to tetrachlorovinphos (TCVP) available for control of arthropod pests of pets in insecticide impregnated pet collar formulations
- Numerous other insecticide formulations (ie. EPA regulated shampoos, sprays, dusts, dips, spot-ons, and FDA regulated oral treatments) are available for control of fleas and ticks on pets.
- Both collars and spot-on formulations are readily available, should be considered as interchangeable, and control the same pest spectrum as TCVP-based pet collars
- However, the purchase decision will be influenced by socioeconomic factors influencing both the buyer's choice of product formulation and also the availability of alternatives in the market place.

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Etofenprox based spot-ons were identified as the most likely alternative to TCVP for both cats and dogs. No increased cost or socio-economic impact would be expected from the use of etofenprox spot-ons. In contrast, increased costs and socio-economic impacts could result from the use of other spot-on formulations and pet collars.

Hazard Characterization



- Risk assessment endpoints based on 10% inhibition of AChE in brain or red blood cells
 - Long-standing, vetted policy for using cholinesterase inhibition data
 - Use benchmark dose modeling
- For risk assessment, only acute exposure durations are a concern for neurotoxic effects
 - Repeated daily exposures do not result in increased inhibition

Residential Handler and Post-application Risk Assessment

- Heading (non cancer)
 - Line
- Heading (cancer)
 - Line

PRD is checking Gowan's comments regarding foliage density to see if it impacts these proposed buffer decisions.

Cancer Risk Estimates

- Cancer risk estimates have also been estimated for TCVP:
 - Dietary range: 10^{-7} (pending)
 - Residential handler range: 10^{-9} to 10^{-7}
 - Residential post-application range: 10^{-7} to 10^{-5}
 - Occupational handler range: 10^{-10} to 10^{-4}
- Cannot make aggregate safety finding based on potential dietary and residential risks.
- Value pending as dietary input was highly refined and needs to be reviewed.

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PRD is checking Gowan's comments regarding foliage density to see if it impacts these proposed buffer decisions.

Dietary Exposure and Risk Assessment



- A
 - A
 - B
 - C
- A
 - A
 - B
 - C

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USDA Pesticide Data Program (PDP)

Endpoints are based on AChEI

Includes 10X safety factor for NOAEL to LOAEL extrapolation for inhalation

Drinking water refinements include:

Use of PCA adjustments for surface water EDWCs

Distribution of daily averages for surface water EDWCs

Elimination of EDWCs for certain crops with specific soil pH preferences (based on disparate degradation profile for acidic vs neutral/alkaline soils)

Mapping of known drinking water sources overlaid with acidic soil locations (where chemical is most persistent)

(The time to peak inhibition for NMCs is typically between 15 to 45 minutes, while complete recovery of the enzyme is achieved within minutes to hours - The CCA study in rats found that peak inhibition occurs within 30-40 minutes for adult and post-natal day (PND) 11 pups (MRID 48298401). Estimates of recovery half-lives in the CCA demonstrate that recovery is longer in the PND11 pups (Brain = 9.5 hours) as compared to adult rats (Brain = 4.26 hours)). HED does acknowledge that based on time course data reported in Padilla et al (2007) study in which adult rats were analyzed with the radiometric assay, the adult half-life for formetanate was approximately 4 hours for the brain. This 4 hour half-life is longer than most of the NMCs which is typically 1 to 2 hours (2007 NMC CRA) and may suggest somewhat different pharmacokinetics for formetanate. However, at this time, data are too limited to make any determination with respect to how formetanate could interact differently with AChE enzyme compared with other NMCs.

Occupational Risk Assessment



- A
 - B
 - C
- A
 - A
 - B
 - C

Occupational Post-application Risk Assessment

- A
 - A
 - B
 - C
- A
 - B
 - C

Draft Ecological Risk Assessment



- Residues can pass through livestock and remain active in manure.
- The ecological DRA identified risks to birds, mammals, and freshwater invertebrates.
- DRA did not quantify risks to terrestrial invertebrates; however, based on available data terrestrial invertebrate risk.
- Single incident with bird categorized as highly probable.
- Tier 1 suite of laboratory-based studies of honey bees incomplete; missing acute/chronic oral toxicity for adult and larval bees.
- In March 2016 during 60-day comment period, EPA received comments on the EFED DRA from the United States Dept. of Agriculture (USDA), Bayer (registrant), and Centers for Biological Diversity (CBD) that are addressed in the EPA's *"Response to Comments on the Preliminary Ecological Risk Assessment for Tetrachlorvinphos (TCVP)"*.

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The ecological DRA identified risks to birds (chronic RQs: 0.5 – 87), mammals (acute RQs <0.1 – 9.2; chronic RQs 0.05 – 8.35), and freshwater invertebrates (acute RQs 0.34 – 0.8; chronic RQs 5 – 9).

DRA did not quantify risks to terrestrial invertebrates; however, based on available data terrestrial invertebrate risk (adult acute contact RQ 0.078 - 0.77).

The Tier suite of laboratory-based acute and chronic toxicity studies with adult and larval bees is incomplete as only adult acute contact toxicity data are currently available for TCVP. Although the compound does not have any agricultural uses and is not applied directly to plants, the pass-through of residues in manure represents a potential route of exposure for ground-nesting non-Apis bees. Submission of a complete set of Tier 1 honey bee toxicity data is needed for TCVP to fully assess Tier 1 risk to individual bees. Pending the results of Tier 1 studies, additional higher-tier data (e.g., nectar and pollen residue data and/or semi-field studies at environmentally relevant concentrations) may be useful for refining the understanding of potential exposure of bees from registered uses, and the extent of risk at the colony level.

Comments on Draft Risk Assessments



- Received comments from ## of commenters and who
 - A
 - B

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Next Steps



- Prepare and issue response to NRDC's 2009 petition by July 21
- Revised Human Health Draft Risk Assessment scheduled for Q3 (June)
- Proposed Interim Decision scheduled for FY 2020 Q1